

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>		Work Assignment Number 1-03 <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:								
Contract Number EP-C-10-030	Contract Period 06/01/2010 To 05/31/2012 Base                      Option Period Number 1	Title of Work Assignment/SF Site Name Health Effects Screening								
Contractor TOXSERVICES LLC		Specify Section and paragraph of Contract SOW								
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance From 06/01/2010 To 05/31/2011								
Comments:										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period: 06/01/2010 To 05/31/2012		Cost/Fee:		LOE: 0						
This Action:				255						
Total:				255						
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee:		LOE:				
Cumulative Approved:				Cost/Fee:		LOE:				
Work Assignment Manager Name Shirley Harrison						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number 202-566-1107				
_____ (Signature)                      (Date)						FAX Number:				
Project Officer Name Shirley Harrison						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number: 202-566-1107				
_____ (Signature)                      (Date)						FAX Number:				
Other Agency Official Name Shirley Harrison						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number: 202-566-1107				
_____ (Signature)                      (Date)						FAX Number:				
Contracting Official Name Sandra Stargardt-Licis						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number: 513-487-2006				
_____ (Signature)                      (Date)						FAX Number:				

PERFORMANCE WORK STATEMENT  
TECHNICAL AND REGULATORY SUPPORT FOR THE DEVELOPMENT  
OF CRITERIA/LIMITS FOR WATER MEDIA (TOXICOLOGY EMPHASIS)

1.0 INTRODUCTION

1.1 Background

The mission of the United States Environmental Protection Agency's Office of Water (OW) under the Safe Drinking Water Act and the Clean Water Act includes protecting the public health from the adverse effects of pollutants (e.g., chemicals and pathogens) in media such as ground and surface waters, drinking water, wastewater, sewage sludge, and sediments. In fulfillment of this mission, OW's Office of Science and Technology (OST) develops effluent guidelines, human health criteria, health advisories, maximum contaminate level goals, and limits for pollutants in various water media.

1.2 Purpose of Contract

The purpose of this contract is to provide technical and regulatory support services to the Health and Ecological Criteria Division (HECD) in OST for the development of human health criteria, health advisories, maximum contaminant level goals, and pollutant limits. This support includes activities such as conducting literature search and literature reviews; conducting hazard, exposure and risk assessments; performing statistical analyses; evaluating pollutants selected for review by the United States Environmental Protection Agency (EPA); assessing the potential impact of criteria on sensitive populations; preparing criteria documents; preparing health advisories, preparing technical guidance documents, preparing technical support documents for regulatory requirements; preparing the index of references for proposed and final regulations; summarizing comments on proposed regulations; and arranging and conducting workshops.

2.0 GENERAL TASKS

2.1 The Contractor shall furnish all facilities, materials, equipment, and necessary professional, technical, and support personnel in support of the effort delineated below. The initial submission of all documents shall be in draft form for EPA review and comment. Required revisions will be provided to the Contractor by EPA for incorporation into a final document.

2.2 The Contractor shall possess or have access to appropriate equipment/software to perform mathematical modeling and statistical analyses in support of criteria development.

2.3 The Contractor shall develop documents and data bases using EPA standard software (e.g. Word, Excel, Lotus Notes and Power Point), as specified in a work assignment. Software documentation shall be accessible to the EPA Work Assignment Manager (WAM) and other persons authorized by the EPA Project Officer (PO).

2.4 The Contractor shall possess or have access to a laboratory that can analyze pollutants (e.g., organic pollutants using gas chromatography/mass spectrometry, metals using atomic absorption) in water media (e.g., wastewater, surface water, drinking water, and sewage sludge), as specified in a work assignment.

2.5 The Contractor shall prepare a Quality Assurance Project Plan (QAPP) for work assignments that require environmental measurements or the use of secondary data.

2.6 The Contractor shall handle all Toxic Substances Control Act (TSCA) and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) confidential business information (CBI) in accordance with the clauses in Section H of this contract. The Contractor shall also comply with the security requirements found in the FIFRA

Information Security Manual and the TSCA Confidential Business Information Security Manual.

2.7 The Contractor shall provide information that will be used by EPA for quick responses and analyses of options, issues, and policy decisions as they relate to the tasks in this Performance Work Statement (PWS). Quick responses are those that require completion in one to seven days, or as specified in a work assignment. EPA will review results of all Contractor analyses, and make a final determination with regard to program objectives and policy decisions.

2.8 The Contractor shall comply with the requirements for studies and rulemaking records contained in authorities such as the Administrative Procedures Act, the Paperwork Reduction Act, the Clean Water Act, OMB Circular A-130 for management of Federal Information Resources, and the Federal Rules of Appellate Procedure (Rules 16 and 17, 28 U.S.C. Appendix).

2.9 The Contractor shall perform the specific tasks in the PWS in accordance with the appropriate EPA risk assessment guidance and science policy guidance (e.g., guidance on the development of a risk reference dose for a non-carcinogen), as indicated in a work assignment.

### 3.0 SPECIFIC TASKS

#### 3.1 Human Health

3.1.1 The Contractor shall prepare summaries of peer-reviewed literature on toxicity, clinical and epidemiological endpoints, as specified in a work assignment. Each summary shall discuss the test protocol (e.g., endpoints measured; test animal; the number, sex, and species of animals in the control group and dosing groups; the method, frequency, and duration of dosing; and sacrifice and pathology data), and shall evaluate the test protocol with respect to EPA published test requirements under TSCA and FIFRA. Similarly, for epidemiological studies, the Contractor shall evaluate the protocol, type of study (e.g., case-controlled, community, prospective, or retro prospective), analyses, and conclusions according to Bradford-Hill criteria.

3.1.2 The Contractor shall prepare screening analyses that display and compare all available data for a pollutant, and build on the summaries in subsection 3.1.1. If required by the work assignment, these analyses shall be presented as electronic data bases.

The Contractor shall be able to develop figures, tables or other graphics to display the array of available data for a pollutant building on the summaries in subsection 3.1.1. The requested data arrays may be requested to assist in risk communication, facilitate the dose-response assessments and improve the transparency of health effects support documents.

The Contractor shall collect data, prepare screening analyses and participate in the development of screening methodologies for chemical contaminants that will be useful in the development of future Contaminant Candidate Lists (CCLs), prioritizing resources, and in identifying emerging contaminants.

3.1.3 The Contractor shall be familiar with the EPA Toxics Release Inventory data base, and other Federal and private release and exposure data bases. The Contractor shall document the methodology, assumptions, and rationales used in the analyses. EPA will make the final decision concerning a finding based on the appropriate technical information and Agency policy.

3.1.4 The Contractor shall prepare, evaluate, and revise health effects documents. These documents provide information on the criteria that protect human health from exposure to a chemical in water media. The Contractor shall document the

methodology, assumptions, and rationales used for this task. EPA will make the final decision concerning a health effects document based on the appropriate technical information and Agency policy.

A health effects document for a chemical shall address, as specified in a work assignment: (1) physical and chemical properties of the chemical; (2) occurrence in water and other media, (3) environmental fate and transport; (4) toxicokinetics; (5) human exposure to the chemical; (6) health effects in animals and humans; (7) mechanisms of toxicity; (8) magnitude of carcinogenic and non- carcinogenic effects including the relative source contribution ; (9) risk characterization, and (10) any other areas set forth in the work assignment. Examples of documents the Contractor shall prepare include the documents that support CCL Regulatory Determinations, documents for six-year review of regulations which may be considered for revision if new data suggests revision, drinking water regulations and development of human health criteria for ambient water. Standard EPA formats for these documents will be provided by the EPA PO/WAM. During the development of a health effects document, the Contractor shall conduct literature reviews to augment the file of references provided by the EPA WAM with other references.

3.1.5 The Contractor shall prepare, evaluate, and revise health advisories for chemicals. A health advisory provides information that public health officials use to help determine control priorities for pollutants in water media (e.g., drinking water, surface water, and sediments) as well as general information for the public. The Contractor shall document the methodology, assumptions, and rationale used to prepare, evaluate, and revise a health advisory. EPA will make the final decision concerning a health advisory based on the appropriate technical information and Agency policy.

A health advisory for a chemical shall address: (1) general information and properties of the chemical; (2) occurrence and environmental fate and transport; (3) pharmacokinetics; (4) health effects in animals and humans; (5) quantification for carcinogenic and non-carcinogenic effects, (6) treatment technologies; (7) analytical methods; (8) risk characterization; and (9) any other areas set forth in the work assignment. During the development of a health advisory, the Contractor shall conduct literature reviews to augment the file of references provided by the EPA WAM with other references.

3.1.6 The Contractor shall provide technical support during the preparation, evaluation, and revision of hazard, exposure, or risk assessment/characterization techniques or methodologies for human health protection. This includes, among other things, providing technical support during the development of methodologies used to develop human health criteria for various water media (e.g., surface water and drinking water). The Contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning a technique or methodology based on the appropriate technical information and Agency policy.

3.1.7 The Contractor shall provide on a rapid response basis analyses of human health risk assessment guidelines, results of human health risk assessments, and treatment technology practices and procedures. This includes, among other things, analysis of the impact of criteria on sensitive populations, and analyses of dose response data, pharmacokinetics data, exposure data, and bioaccumulation data.

3.1.8 The Contractor shall prepare, evaluate, and revise technical guidance documents for chemicals. These documents provide information on the principles for criteria development (e.g., minimum data requirements and exposure assumptions). The Contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning a technical guidance document based on the appropriate technical information and Agency policy.



3.1.9 The Contractor shall evaluate "raw" data generated from a toxicity study. The raw data will be provided by the EPA WAM. The evaluation shall include a complete description of the protocol used to gather the data; analyses of effects observed including tabulation of all observations and pathology for individual test animals; evaluation of biological significance of endpoints according to EPA published guidelines or other technical documents; statistical analyses of significance of observations; and conclusions as to existence of treatment-related effects and their implications for human health. If required by a work assignment, the Contractor shall engage and convene a panel of experts to conduct a review of tissue preparations and slides from the test to characterize and classify lesions observed.

3.1.10 The Contractor shall conduct Monte Carlo or similar statistical uncertainty analyses of toxicity or epidemiological endpoint incidence data or exposure data, as specified in a work assignment. These analyses shall be completed in accordance with EPA published guidance.

The Contractor shall model the dose response data from cancer and noncancer studies using benchmark dose, categorical regression or other similar methodologies developed by the Agency as specified in a work assignment. These analyses shall be completed in accordance with EPA published guidance for the methodology used.

3.1.11 The Contractor shall provide analyses of food consumption patterns and associated intake of pollutants for the U.S. population. These shall include frequency and amount of specific foods consumed by sex, age, and geographical locations. Data to be analyzed shall include data from Federal data collection efforts, State collection efforts, and other available studies. Similarly, the Contractor shall provide analyses of exposure data from the Center for Disease Control National Health and Nutrition Examination Survey (NHANES) data base and the EPA National Human Exposure Assessment Survey data base.

3.1.12 All of the above tasks and deliverables shall be completed in accordance with EPA published guidelines (e.g., carcinogenic risk assessment guidelines, reproductive risk assessment guidelines, developmental risk assessment guidelines, neurotoxicity guidelines, exposure assessment guidelines, risk characterization policy guidelines, benchmark dose guidelines or Monte Carlo guidelines).

### 3.2 Sewage Sludge

3.2.1 The Contractor shall provide technical support during the preparation, evaluation, and revision of procedures for selecting pollutants-of-concern in sewage sludge that is used or disposed of, and shall provide technical support during the evaluation of those pollutants. The Contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning the procedure used to select pollutants-of-concern and the evaluation of those pollutants based on the appropriate technical information and Agency policy.

3.2.2 The Contractor shall conduct exposure pathway risk assessments for pollutants in sewage sludge applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator. The pathways evaluated for each use or disposal practice shall be the pathways evaluated for each practice when the Standards for the Use or Disposal of Sewage Sludge (40 CFR Part 503) were developed, and other pathways specified in a work assignment. Results of the risk assessments will be used by EPA to develop limits for pollutants in the sewage sludge.

3.2.3 The Contractor shall prepare, evaluate, and revise technical support documents for a standard for the use or disposal of sewage sludge. These documents

contain the rationales for the requirements (i.e., general requirements; pollutant limits; management practices; operational standards; and frequency of monitoring, record keeping, and reporting requirements) in a sewage sludge use or disposal standard (see 40 CFR Part 503).

The Contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning a technical support document based on the appropriate technical information and Agency policy.

### **3.3 Statistics Support**

3.3.1 The Contractor shall have statistical analyses capabilities to perform analyses of environmental data for toxicological pollutants to derive descriptive or interpretative statistics.

3.3.2 The Contractor shall conduct laboratory/field studies to support the development of water quality criteria, maximum contaminant level goals, sewage sludge pollutant limits, and other program requirements, as specified in a work assignment.

### **3.4 Administrative Record Support**

The Contractor shall provide data and documentation to be used by EPA in the analysis of technical issues and options for proposed and final regulations, as specified in a work assignment. Deliverables under this task include data summaries, technical reports, option papers, issue papers, and public and confidential records and files. The Contractor shall describe and document the data gathering activities; display, characterize, and interpret the data and information collected; obtain copies of any references used; and describe all methodologies used. Written reports and corresponding records and files shall be prepared and organized, indexed, and cross-referenced in an administrative record for a proposed or final regulation so that the analyses and conclusions can be reproduced based on the information in the administrative record for a proposed or final regulation.

### **3.5 Rule making support**

The Contractor shall index and summarize public comments on proposed regulations. Using information provided by EPA (i.e., typically public comments submitted in response to a proposed regulation and information collection requests), the Contractor shall prepare an index of issues in the information provided by EPA, and cross reference those issues to the public comments. For technical issues assigned by the EPA WAM, the Contractor shall, based on knowledge of the appropriate rule making, prepare draft technical responses to the issues in the public comments including all relevant citations to the administrative record. EPA will review the draft technical responses, and prepare the final responses to the comments.

### **3.6 Preparation of outreach materials**

3.6.1 The Contractor shall develop outreach materials in support of the tasks in this PWS. These materials include brochures, presentation boards, slide shows, fact sheets, pamphlets, posters, videos, INTERNET layouts, and models. The materials shall be developed for use in media events (e.g., press releases). In addition, the Contractor shall provide materials for distribution at presentations. All materials shall be provided in accordance with the limitations set for in the Section H clause titled "PRINTING (EPAAR 1552.208-70)." The Contractor shall provide a draft of all materials for approval by the EPA WAM, and shall prepare the final materials based on the EPA WAM's comments on the draft materials. For print products, the Contractor shall provide a camera-ready copy and a disk copy in a disk format that enables the material to be loaded onto the INTERNET. This task only shall be done in direct support of the technical requirements in

this PWS.

3.6.2 The Contractor shall provide, when included in a work assignment, a complete and accurate translation of foreign language articles cited in a criteria document, a health advisory, or a technical guidance document. Translations shall be performed by experienced scientific translators well-versed in chemical, toxicological, statistical, biomedical, or epidemiological terminology. The Contractor shall insure that there are no terminology or language usage ambiguities that make interpretation and analysis of the findings difficult. No translations shall be made without the written approval of the Project Officer.

### 3.7 Arranging and conducting workshops

The Contractor shall provide support in arranging workshops, conferences, training sessions, and public meetings, and obtaining appropriate individuals to address various issues. Meeting support shall be limited in scope, and shall cover only those meetings required to address the requirements in this PWS. The Contractor shall arrange travel only in accordance with the authority and limitations in the Section H clause titled "APPROVAL OF CONTRACTOR TRAVEL" (i.e., use of contract funds to reimburse travel is strictly limited to logistical support for speakers, scientists, and experts who contribute directly to the requirements of a task in this PWS). The Contractor shall support EPA by: (1) providing information for meeting agendas, including typing the agendas; (2) preparing drafts of technical information for use in preparing briefing materials; (3) identifying and inviting speakers and experts to participate in a workshop; (4) arranging for meeting space when Government space is not available; (5) arranging for the appropriate audio-visual equipment; (6) providing advance announcements, registration support, visual aid preparation, logistical support, case study preparation, interactive and role-playing activity development; and (7) preparing the minutes of the meeting, including the meeting results, for approval by the EPA PO/WAM.

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>		Work Assignment Number 1-03								
		<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001								
Contract Number EP-C-10-030		Contract Period 06/01/2010 To 05/31/2012 Base                      Option Period Number 1								
Contractor TOXSERVICES LLC		Title of Work Assignment/SF Site Name Health Effects Screening								
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance From 06/01/2011 To 05/31/2012								
Comments:										
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund           <div style="flex-grow: 1; text-align: center;">Accounting and Appropriations Data</div> <input checked="" type="checkbox"/> Non-Superfund         </div>										
SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:				LOE: 255				
06/01/2010 To 05/31/2012										
This Action:						300				
Total:						555				
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee:		LOE:				
Cumulative Approved:				Cost/Fee:		LOE:				
Work Assignment Manager Name Octavia Conerly						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number 202-566-1094				
						FAX Number:				
Project Officer Name Shirley Harrison						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number: 202-566-1107				
						FAX Number:				
Other Agency Official Name Shirley Harrison						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number: 202-566-1107				
						FAX Number:				
Contracting Official Name Sandra Stargardt-Licis						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number: 513-487-2006				
						FAX Number:				

**PERFORMANCE WORK STATEMENT  
TOXSERVICES CONTRACT #EP-C-10-030  
WORK ASSIGNMENT #1-03 AMD #1**

**TITLE: Health Effects Screening Approach for Pharmaceuticals – National Academy of Sciences Follow-up**

**EPA Work Assignment Manager**

Octavia Conerly  
U.S. Environmental Protection Agency  
Office of Science and Technology, Office of Water  
Health and Ecological Criteria Division  
1200 Pennsylvania Ave., NW MC 4304T  
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**Estimated Number of Hours: 300**

**Period of Performance:** WA Issuance (Amd) through May 31, 2012

**BACKGROUND** – Same as original work assignment

**QUALITY ASSURANCE** – Same as original work assignment

**PURPOSE:** The purpose of this amendment is to add new tasks, funding and hours to the existing work assignment. Any technical direction under this work assignment amendment, the EPA WAM will provide to the PO and CO within 5 calendar days.

**TASKS**

**Task 0 - Workplan and Monthly Progress Report** – same as original work assignment

**Task 14 – Continue Work on Final Draft Report**

In addition to the incorporation of comments, the contractor shall perform the following analysis for inclusion in the report:

***Subtask 14.1: Analysis of Maximum Recommended Starting Dose (MRSD) and s-MRSD (screening-MRSD) values; EPA meeting***

Upon receipt of FDA's MRSD values for 4 groups of pharmaceuticals from the EPA WAM, the contractor shall compare FDA's values to screening MRSD values included in the draft drug summaries. Once the contractor has made these comparisons, the contractor shall participate in an EPA meeting. The EPA WAM will notify the contractor of the date/time of the meeting.

Deliverable:	MRSD comparisons; participation in EPA meeting	4 weeks following receipt of FDA MRSD values
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#### ***Subtask 14.2: Development of Benchmark Values***

Once decisions have been made regarding utility of MRSD values and upon receipt of occurrence data summaries for the 4 groups of pharmaceuticals from the EPA WAM, the contractor shall use the occurrence concentration data and the health effects data (MRSD or other health data) for the 4 groups of pharmaceuticals to develop benchmark values similar to health reference levels used by OW to screen drinking water contaminants. The contractor shall carefully document each step of the development process to include in the final draft report. The contractor shall submit a revised final draft of the report to the EPA WAM for review.

Deliverable: Submission of revised final draft report      4 weeks following receipt of EPA WAM comments

#### **Task 15 – Technical Support**

The contractor shall provide technical support to the EPA WAM to include the review and finalization of the draft "Methodology for Risk-Based Prioritization of Pharmaceutical Residues in Finished Drinking Water for Human Health Risk Assessment" paper originally prepared by the Food and Drug Administration. Comments will be submitted to the contractor by the EPA WAM.

Deliverable: Finalization of prioritization paper      4 weeks following receipt of EPA WAM comments

#### **Task 16 – Preparations for Professional Meetings**

The contractor shall prepare a presentation focusing on the screening and prioritization of groups of pharmaceuticals using health effects data for the Society for Risk Analysis (SRA) and Society of Toxicology (SOT) annual meetings. This task is subject to SRA and SOT's acceptance of the abstracts on this material. The contractor shall submit each presentation for EPA WAM review.

Deliverable: Presentations for meetings      2 weeks prior to the SRA and SOT deadlines

**TRAVEL:** The contractor is required to make 2 trips under this work assignment amendment. One trip to EPA (Washington, DC area) for review of the analyses and reports with the EPA WAM, and one trip to the SRA annual meeting in Charleston, SC to present material on grouping pharmaceuticals using health effects data. Any travel related to this work assignment amendment must be approved by the EPA WAM and PO in advance.

**EPA**United States Environmental Protection Agency  
Washington, DC 20460**Work Assignment**

Work Assignment Number

1-04

☐ Other ☐ Amendment Number:

Contract Number

EP-C-10-030

Contract Period 06/01/2010 To 05/31/2012

Base

Option Period Number 1

Title of Work Assignment/SF Site Name

Perchlorate Health Effects

Contractor

TOXSERVICES LLC

Specify Section and paragraph of Contract SOW

2.1 - 2.3, 2.5, 2.7 - 2.9, 3.1.1 - 3.1.12, 3.3.1, 3

Purpose:



Work Assignment



Work Assignment Close-Out



Work Assignment Amendment



Incremental Funding



Work Plan Approval

Period of Performance

From 06/01/2011 To 05/31/2012

Comments:



Superfund

## Accounting and Appropriations Data



Non-Superfund

SFO  
(Max 2)

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

## Authorized Work Assignment Ceiling

Contract Period:

Cost/Fee:

LOE: 0

06/01/2010 To 05/31/2012

This Action:

157

Total:

157

## Work Plan / Cost Estimate Approvals

Contractor WP Dated:

Cost/Fee:

LOE:

Cumulative Approved:

Cost/Fee:

LOE:

Work Assignment Manager Name Melanie Young

Branch/Mail Code:

Phone Number 202-250-8817

FAX Number:

(Signature)

(Date)

Project Officer Name Shirley Harrison

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

(Signature)

(Date)

Other Agency Official Name

Branch/Mail Code:

Phone Number:

FAX Number:

(Signature)

(Date)

Contracting Official Name Sandra Stargardt-Licis

Branch/Mail Code:

Phone Number: 513-487-2006

FAX Number:

(Signature)

(Date)

**PERFORMANCE WORK STATEMENT  
TOXSERVICES CONTRACT #EP-C-10-030  
WORK ASSIGNMENT # 1-04**

**TITLE:** Perchlorate Health Effects Support Document (HESD)

**WORK ASSIGNMENT**

**MANAGER:**

**Melanie Young**  
Mail Code 4304T, Room #5231YY  
Office of Water, Office of Science and Technology  
Health and Ecological Criteria Division  
United States Environmental Protection Agency (USEPA)  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460  
Telephone: 202-250-8817; Fax: 202-566-1140

**PERIOD OF PERFORMANCE:** Work Assignment Issuance through May 31, 2012

**SOW TASKS:** 2.1 - 2.3, 2.5, 2.7 - 2.9, 3.1.1 - 3.1.12, 3.3.1, 3.4, 3.5, 3.6.1, 3.6.2.

**LOE:** 157 hours

**BACKGROUND:**

The mission of the United States Environmental Protection Agency's (EPA) Office of Water (OW) under the Safe Drinking Water Act and the Clean Water Act includes protecting the public health from the adverse effects of pollutants (e.g., chemicals and pathogens) in media such as surface water, drinking water, wastewater, sewage sludge, and sediments. In fulfillment of this mission, OW's Office of Science and Technology (OST) develops effluent guidelines, human health criteria, health advisories, maximum contaminant level goals, and limits for pollutants in various water media. This work assignment directly supports the Health and Ecological Criteria Division's (HECD) mission to produce and publish scientifically sound, usable, and implementable methods, guidance, and criteria that may be utilized to protect human health in drinking water and human health in ambient water and sediment.

A Health Effects Support Document (HESD) for the chemical perchlorate is being prepared to support a newly proposed positive regulation for perchlorate in drinking water. U.S. EPA's regulatory determination for perchlorate in accordance with the Safe Drinking Water Act (SDWA) was published in the Federal Register (*FR Vol. 76, No. 29, p. 7762*) on February 11, 2011. EPA has determined that perchlorate meets SDWA's criteria for regulating a contaminant. Specifically, EPA has determined that perchlorate may have an adverse effect on the health of persons, that perchlorate is known to occur or there is a substantial likelihood that perchlorate will occur in public water systems with a frequency and at levels of public health concern, and that in the sole judgment of the Administrator, regulation of perchlorate in drinking water systems presents a meaningful opportunity for health risk reduction for persons served by public water systems. Therefore, EPA has initiated the process of developing and establishing a national primary drinking water regulation (NPDWR) for perchlorate.

## **QUALITY ASSURANCE:**

The tasks in this work assignment require only the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must supplement their quality assurance project plan (QAPP) to assure the quality of the secondary data used under this work assignment. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1, below. The tasks in this Work Assignment (WA) do not require primary data from environmental measurement and/or generation of laboratory data.

## **PERFORMANCE WORK STATEMENT:**

The purpose of this work assignment is to provide supplementary scientific health effects analyses for perchlorate to the EPA WAM. Specifically, this amendment requires the critical evaluation, qualitative, and quantitative analyses of human (as well as any animal) data relevant to potentially adverse human health effects of perchlorate that have been published in the scientific literature primarily from the start of the year 2004. U.S. EPA's objective is to develop an all-encompassing weight-of-evidence approach for developing the final perchlorate HESD, and for subsequently developing the Maximum Contaminant Level Goal (MCLG) and Maximum Contaminant Level (MCL) for perchlorate, in support of the newly proposed positive EPA drinking water regulatory determination for perchlorate.

The EPA WAM will be the point of contact for all of the technical and scientific aspects of each of the tasks. Technical directions may be issued only by the EPA WAM to clarify or add specification to the task descriptions provided under this PWS. If the contractor cannot commence work, for any reason whatsoever, after issuance of technical directions by the EPA WAM, the contractor shall notify the EPA WAM in writing by email, with a copy to both the PO and CO, and provide in this communication a projected start date for commencement of work. For any verbal technical direction issued by the EPA WAM under this work assignment, the EPA WAM shall provide a copy to the PO and CO within 5 days.

The contractor shall independently prepare and submit all drafts/templates/final documents, including text documents, tables, databases, or graphical display deliverables. The contractor shall initiate work on deliverables sequentially, i.e., Task #1, then Task #2, etc. The contractor shall submit all deliverables using any specific appropriate software application in the Microsoft Office 2007 complete software package, for any and all deliverables, to the EPA WAM for review prior to submission of any final product (where a final product is required). For any documents, tables, databases, or graphical display deliverables, the complete Microsoft Office 2007 software package is the software that EPA currently uses, and requires the contractor to use for any deliverables for this work assignment. The complete Microsoft Office 2007 software package includes Microsoft Office Access 2007, Microsoft Office Excel 2007, Microsoft Office InfoPath 2007, Microsoft Office PowerPoint 2007, Microsoft Office Publisher 2007, and Microsoft Office Word 2007. Drafts submitted by the contractor shall clearly specify the methods, procedures, considerations, assumptions, relevant citations, data sources, and data that support any conclusions and recommendations, where necessary. For this work assignment, revisions by the contractor of any draft deliverables for all specified tasks will be entirely contingent upon receipt of comments only from the EPA WAM. All drafts and final products shall be completely free of any and all typographical and/or grammatical errors. The contractor shall incorporate all of the EPA WAM's

technical directions and comments into any draft and/or final deliverables, where applicable.

## **TASKS:**

### **Task 1. Work Plan and Monthly Progress Reports**

The contractor shall develop a work plan to address all tasks in this performance-based work assignment. The work plan shall include a schedule, a staffing plan, level of effort (LOE) computed by specific task and cost estimate for each task, the key assumptions on which staffing plan and budget are based, the professional qualifications, including resumes, of any proposed staff to complete the specified work assignment tasks, and a project specific supplement to the contract-level QAPP.

The scientific disciplines and level of expertise required for providing supplementary scientific health effects analyses for this performance work statement are listed as follows: for Task #2, a PhD in epidemiology, and for Task #3, a PhD in toxicology. The sufficiency of the required academic and subject matter expertise shall be determined by the EPA WAM. The professional qualifications, including resumes, of any proposed staff to complete the specified work assignment tasks shall be submitted by the contractor at the same time as the work plan submission, and must be approved by the EPA WAM along with the work plan, prior to commencement of any further work on this work assignment. Since the stated scientific disciplines are required for this work assignment, if the contractor cannot locate staff possessing the stated academic background, the contractor shall provide a statement as to the search efforts, availability, or unavailability of staff in these specific scientific disciplines of epidemiology and toxicology directly in the work plan.

The contractor's estimated LOE may differ from that estimated by EPA in the work assignment but the overall LOE shall not exceed the total LOE specified in the work assignment submittal. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All "P" levels, hours, and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The work plan shall also provide an analysis of the existing and projected constraints, and the feasibility of accomplishing the project's purpose. The contractor shall include a separate table that summarizes the financial reporting for each task to be included with the monthly progress reports. The separate table shall provide greater detail of the progress on each task and its financial status in sufficient detail for the EPA WAM to assess progress relative to the task expenditures.

In addition, the contractor shall prepare a project-specific supplement to the contract level QAPP to ensure the quality of any secondary data used to complete these tasks. In any final reports required, the contractor shall summarize the QA measures and processes used and incorporated in the work assignment.

A separate tracking monthly summary must be prepared for the EPA WAM using the following format:

WA # and Task#	Task Description	Initial Budget	Current Month Cost	Projected Cost for Following Month	Balance Remaining
WA B-XX Task 1	Work Plan and Monthly Reports	\$7,000.00	\$350.00	\$350.00	\$6,650.00
WA B-XX Task 2	Draft document preparation	\$7,000.00	\$350.00	\$350.00	\$6,650.00
Total		\$14,000.00	\$700.00	\$700.00	\$13,300.00



## **Task 2. Evaluation and Draft Table Summary of New Literature Relevant to Perchlorate Health Effects**

The contractor shall evaluate literature/data provided specifically by the EPA WAM, and develop a draft summary table of relevant information extracted from this evaluation (e.g., study population, study design, exposure/outcome variables, exposure/outcome assessment, health outcome statistics, etc.). This task relates directly, but not exclusively, to contractor capabilities and work products as stated in section 3.1.1 of the EP-C-10-030 Performance Work Statement, which form the basis for EPA's expectations for this task. The contractor shall prepare the contents of this draft summary table as specified by technical direction from the EPA WAM; the technical direction will include up to 14 published papers (provided as electronic files) representing the literature to review, evaluate, and incorporate into the draft summary table. The contractor shall provide the draft summary table to the EPA WAM, and this draft deliverable shall be submitted to EPA WAM in draft memorandum format. The initiation of Task #2 and provision of any technical direction for this task is contingent upon EPA WAM approval of the work plan and/or contractor submission of any required revisions to the work plan, and contractor submission and EPA WAM approval of resumes of any proposed staff submitted by the contractor as required by Task #1.

## **Task 3. Develop and Draft Dose/Exposure-Response Graphical Arrays across Human Health and Animal Studies of the Health/Biological Effects of Perchlorate Exposure**

The contractor shall independently develop and prepare draft graphical arrays of dose/exposure-response characteristics of human health and animal studies provided specifically by the EPA WAM, describing the adverse biological/health effects of perchlorate exposure. This task relates directly, but not exclusively, to contractor capabilities and work products as stated in section 3.1.2 of the EP-C-10-030 Performance Work Statement, which form the basis for EPA's expectations for this task. The contractor shall prepare the format/contents of the deliverable for this task as specified by technical direction from the EPA WAM; the technical direction will include up to 26 published papers (provided as electronic files) representing the literature to review, evaluate, and incorporate into the draft graphical arrays. The contractor shall independently develop the format/contents for this draft deliverable, shall provide the draft deliverable to the EPA WAM, and this draft deliverable shall be submitted to EPA WAM in draft memorandum format. The initiation of Task #3 and provision of any technical direction for this task is contingent upon adequate progress on Task #2, as determined by the EPA WAM.

### **SCHEDULE AND DELIVERABLES:**

- Task 1.**        **Fifteen (15) days** after receipt of the work assignment (**Work Plan and required resumes of any proposed staff**).
- Task 2.**        **Fourteen (14) calendar days** after receipt of technical direction from the EPA WAM (**Summary Health Effects Literature Evaluation Tabulation Draft**). The initiation of Task #2 is contingent upon EPA WAM approval of the work plan and/or contractor submission of any required revisions to the work plan from Task #1.
- Task 3.**        **Fourteen (14) calendar days** after receipt of technical direction from the EPA WAM (**Perchlorate Health/Biological Effects Dose/Exposure-Response Studies Graphical Arrays Draft**). The initiation of Task #3 is contingent upon adequate progress on Task #2, as determined by the EPA WAM.

**TRAVEL:** No travel is required under this work assignment. Any subsequent inquiries from the contractor for unanticipated travel directly chargeable only to this work assignment must be submitted two weeks in advance and approved by both the EPA WAM and the EPA Project Officer, before any such travel can take place.

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>		Work Assignment Number 1-05 <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:								
Contract Number EP-C-10-030	Contract Period 06/01/2010 To 05/31/2012 Base                      Option Period Number 1	Title of Work Assignment/SF Site Name Workgroup Perchlorate Review								
Contractor TOXSERVICES LLC		Specify Section and paragraph of Contract SOW 2.1 - 2.3, 2.5, 2.7 - 2.9, 3.1.1 - 3.1.12, 3.3.1,								
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance From 06/01/2011 To 05/31/2012								
Comments:										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE: 0						
06/01/2010 To 05/31/2012										
This Action:				270						
				270						
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee:		LOE:				
Cumulative Approved:				Cost/Fee:		LOE:				
Work Assignment Manager Name    Melanie Young						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number    202-250-8817				
						FAX Number:				
Project Officer Name    Shirley Harrison						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number:    202-566-1107				
						FAX Number:				
Other Agency Official Name						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number:				
						FAX Number:				
Contracting Official Name    Sandra Stargardt-Licis						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number:    513-487-2006				
						FAX Number:				

**PERFORMANCE WORK STATEMENT  
TOXSERVICES CONTRACT #EP-C-10-030  
WORK ASSIGNMENT #1-05**

**TITLE:**      **Workgroup Perchlorate Health Effects Review**

**WORK ASSIGNMENT MANAGER:**      **Melanie Young**  
Mail Code 4304T, Room #5231YY  
Office of Water, Office of Science and Technology  
Health and Ecological Criteria Division  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460  
Telephone: 202-250-8817; Fax: 202-566-1140

**PERIOD OF PERFORMANCE:**      Work Assignment Issuance through May 31, 2012

**PWS TASKS:**      2.1 - 2.3, 2.5, 2.7 - 2.9, 3.1.1 - 3.1.12, 3.3.1, 3.4, 3.5, 3.6.1, 3.6.2.

**LOE:**              **270 Hours**

**BACKGROUND:**

The mission of the United States Environmental Protection Agency's (EPA) Office of Water (OW) under the Safe Drinking Water Act and the Clean Water Act includes protecting the public health from the adverse effects of pollutants (e.g., chemicals and pathogens) in media such as surface water, drinking water, wastewater, sewage sludge, and sediments. In fulfillment of this mission, OW's Office of Science and Technology (OST) develops effluent guidelines, human health criteria, health advisories, maximum contaminant level goals, and limits for pollutants in various water media. This Performance Work Statement (PWS) directly supports the Health and Ecological Criteria Division's (HECD) mission to produce and publish scientifically sound, usable, and implementable methods, guidance, and criteria that may be utilized to protect human health in drinking water and human health in ambient water and sediment.

EPA has recently initiated the process of developing and establishing a national primary drinking water regulation (NPDWR) for perchlorate. In support of this effort, new scientific research has been developed and published relative to potential health effects of perchlorate exposure. In order to analyze this new research in light of EPA's recent determination that perchlorate may have an adverse effect on the health of persons, a special EPA workgroup has been formed to review new science regarding perchlorate. Contractor support is needed to facilitate synthesizing new scientific literature on perchlorate health effects, for subsequent workgroup review.

**QUALITY ASSURANCE:**

The tasks in this PWS require only the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must supplement their quality assurance project plan (QAPP) to assure the quality of the secondary data used under this PWS. The project specific quality assurance requirements must be addressed in the work plan and monthly

progress reports as specified under Task 1, below. The tasks in this PWS do not require primary data from environmental measurement and/or generation of laboratory data.

## **PERFORMANCE WORK STATEMENT:**

The purpose of this PWS is to provide supplementary scientific health effects analyses for perchlorate to EPA. Specifically, this PWS requires the summarization, review, and analysis of human (as well as any relevant animal) data in published reports relevant to potentially adverse human health effects of perchlorate.

The EPA WAM will be the point of contact for all of the technical and scientific aspects of each of the tasks. Technical directions may be issued only by the EPA WAM to clarify or add specification to the task descriptions provided under this PWS. After issuance of technical direction, immediate start shall be expected of the contractor. If the contractor cannot commence work on a given task, for any reason whatsoever, after issuance of technical directions or review comments by the EPA WAM, the contractor shall notify the EPA WAM in writing by email, with a copy to both the PO and CO, and provide in this written communication a projected start date for commencement of work. For any verbal technical direction issued by the EPA WAM under this PWS, the EPA WAM shall provide a copy to the PO and CO within 5 days.

The contractor shall independently prepare and submit all drafts/templates/final documents, including text documents, tables, databases, or graphical display deliverables for this PWS. The contractor shall initiate work on all deliverables when technical direction is provided by the EPA WAM. The contractor shall submit all deliverables using any specific appropriate software application in the Microsoft Office 2007 complete software package, for any and all deliverables, to the EPA WAM. For any documents, tables, databases, or graphical display deliverables, the complete Microsoft Office 2007 software package is the software that EPA currently uses, and requires the contractor to use for any deliverables for this PWS. The complete Microsoft Office 2007 software package includes Microsoft Office Access 2007, Microsoft Office Excel 2007, Microsoft Office InfoPath 2007, Microsoft Office PowerPoint 2007, Microsoft Office Publisher 2007, and Microsoft Office Word 2007. Drafts or final products submitted by the contractor shall clearly specify the methods, procedures, considerations, assumptions, relevant citations, data sources, and data that support any conclusions and recommendations, where necessary. For this PWS, revisions by the contractor of any draft deliverables for all specified tasks will be entirely contingent upon receipt of comments only from the EPA WAM. All drafts and final products shall be completely free of any and all typographical and/or grammatical errors. The contractor shall incorporate all of the EPA WAM's technical directions and comments into any draft and/or final deliverables, where applicable.

## **TASKS:**

### **Task 1. Work Plan and Monthly Progress Reports.**

The contractor shall develop a work plan to address all tasks in this PWS. The work plan shall include a schedule, a staffing plan, level of effort (LOE) computed by specific task and cost estimate for each task, the key assumptions on which staffing plan and budget are based, the



professional qualifications, including resumes, of any proposed staff to complete the specified PWS tasks, and a project specific supplement to the contract-level QAPP.

The scientific disciplines and level of expertise required for providing supplementary scientific health effects analyses for this PWS are advanced degrees in endocrinology (human health sciences) and toxicology. The sufficiency of the required academic and subject matter expertise shall be determined by the EPA WAM. The professional qualifications, including resumes, of any proposed staff to complete the specified PWS tasks shall be submitted by the contractor at the same time as the work plan submission, and must be approved by the EPA WAM along with the work plan, prior to commencement of any further work on this PWS. Since the stated scientific disciplines are required for this PWS, if the contractor cannot locate staff possessing the stated academic backgrounds, the contractor shall provide a statement as to the search efforts, availability, or unavailability of staff in these specific scientific disciplines of endocrinology (human health sciences) and toxicology directly in the work plan.

The contractor's estimated LOE may differ from that estimated by EPA WAM in the PWS but the overall LOE shall not exceed the total LOE specified in the PWS submittal. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All "P" levels, hours, and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The work plan shall also provide an analysis of the existing and projected constraints, and the feasibility of accomplishing the project's purpose. The contractor shall include a separate table that summarizes the financial reporting for each task to be included with the monthly progress reports. The separate table shall provide greater detail of the progress on each task and its financial status in sufficient detail for the EPA WAM to assess progress relative to the task expenditures.

In addition, the contractor shall prepare a project-specific supplement to the contract level QAPP to ensure the quality of any secondary data used to complete these tasks. In any final reports required, the contractor shall summarize the QA measures and processes used and incorporated in the PWS.

A separate tracking monthly summary must be prepared for the EPA WAM using the following format:

WA # and Task#	Task Description	Initial Budget	Current Month Cost	Projected Cost for Following Month	Balance Remaining
WA B-XX Task 1	Work Plan and Monthly Reports	\$7,000.00	\$350.00	\$350.00	\$6,650.00
WA B-XX Task 2	Draft document preparation	\$7,000.00	\$350.00	\$350.00	\$6,650.00
Total		\$14,000.00	\$700.00	\$700.00	\$13,300.00

**Task 2. Develop a Draft Written Report Demonstrating Potential Impacts of Perchlorate Exposure on Thyroid Hormone Levels in Fetuses, Infants, and Pregnant Women, and Describing the Impacts of Thyroid Hormone Decrement in Humans.**

(A) The contractor shall evaluate literature/data available on perchlorate exposure versus thyroid effects to contractor for summarization, review, and analysis. The contractor shall investigate, and, if possible, demonstrate the impact of perchlorate on thyroid hormone levels in fetuses, infants, and pregnant women, and investigate and report on whether there is an effect in the general population.

(B) The contractor shall also evaluate literature/data available on the potential impacts of thyroid hormone decrement in humans. The contractor shall investigate and report on each of the following: 1) whether and how fetuses and infants are biologically similar or different from adults; 2) whether and how effects in fetuses and infants are irreversible and of high impact (as compared with effects in adults being largely metabolic; 3) whether fetuses and infants are or are not euthyroid, so hypothetical changes in thyroid hormone level may have faster onset; 4) whether this makes a case for fetuses, infants, and pregnant women as a sensitive subpopulations; 5) whether and how demonstrating differential sensitivity by life stage is possible; 6) whether population risk as opposed to individual risk can be considered; and, 7) whether and how dietary iodine deficiency and individual biological set points might also be a consideration.

Published papers will be provided by the EPA WAM. The contractor shall prepare the contents of this draft report as specified by technical direction from the EPA WAM; the technical direction will include up to 60 published papers (provided as electronic files) representing the literature to review, evaluate, and incorporate into the draft and final report. The contractor shall independently develop the format/contents for this deliverable, and the contractor shall provide the draft report deliverable to the EPA WAM. This task relates directly, but not exclusively, to contractor capabilities and work products as stated in section 3.1 of the EP-C-10-030 Performance Work Statement, which form the basis for EPA's expectations for this task. The initiation of Task #2 and provision of any technical direction for this task is contingent upon EPA WAM approval of the work plan and/or contractor submission of any required revisions to the work plan, and contractor submission and EPA WAM approval of resumes of any proposed staff submitted by the contractor as required by Task #1.

**Task 3. Develop Final Written Report**

The contractor shall finalize the draft report from Task #2, after receipt of review comments on the draft report in the form of technical direction from the EPA WAM. The contractor shall provide the final report deliverable to the EPA WAM.

**SCHEDULE AND DELIVERABLES:**

**Task 1. Fifteen (15) calendar days after receipt of the work assignment (Work Plan and required resumes of any proposed staff).**

**Task 2.**      **Forty (40)** calendar days after receipt of technical direction from the EPA WAM (**Draft Written Report Demonstrating Potential Impacts of Perchlorate Exposure on Thyroid Hormone Levels in Fetuses, Infants, and Pregnant Women, and Describing the Impacts of Thyroid Hormone Decrement in Humans**). The initiation of Task #2 is contingent upon EPA WAM approval of the work plan and/or contractor submission of any required revisions to the work plan from Task #1.

**Task 3.**      **Eight (8)** calendar days after receipt of technical direction comments on the draft report from the EPA WAM (**Final Written Report from Task #2**).

**TRAVEL:**    No travel is required under this work assignment. Any subsequent inquiries from the contractor for unanticipated travel directly chargeable only to this work assignment must be submitted two weeks in advance and approved by both the EPA WAM and the EPA Project Officer, before any such travel can take place.

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>		Work Assignment Number 1-05
		<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001
Contract Number EP-C-10-030	Contract Period 06/01/2011 To 05/31/2012 Base                      Option Period Number 1	Title of Work Assignment/SF Site Name Workgroup Perchlorate HEReview
Contractor TOXSERVICES LLC		Specify Section and paragraph of Contract SOW
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance  From 06/01/2011 To 05/31/2012
Comments:  ADD Santhini Ramasamy as the Alternate WAM		
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund		
SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A.		
Line	DCN (Max 6) Budget/FY (Max 4) Appropriation Code (Max 6) Budget Org/Code (Max 7) Program Element (Max 9) Object Class (Max 4)	Amount (Dollars) (Cents) Site/Project (Max 8) Cost Org/Code (Max 7)
1		
2		
3		
4		
5		
Authorized Work Assignment Ceiling		
Contract Period: 06/01/2011 To 05/31/2012                      Cost/Fee:                      LOE:		
This Action:		
Total:		
Work Plan / Cost Estimate Approvals		
Contractor WP Dated:		Cost/Fee:                      LOE:
Cumulative Approved:		Cost/Fee:                      LOE:
Work Assignment Manager Name Melanie Young  _____ (Signature) _____ (Date)		Branch/Mail Code: Phone Number 202-250-8817 FAX Number:
Project Officer Name Shirley Harrison  _____ (Signature) _____ (Date)		Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Other Agency Official Name  _____ (Signature) _____ (Date)		Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name Sandra Stargardt-Licis  _____ (Signature) _____ (Date)		Branch/Mail Code: Phone Number: 513-487-2006 FAX Number:

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>		Work Assignment Number 1-05	
		<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000002	
Contract Number EP-C-10-030		Contract Period 06/01/2010 To 05/31/2012 Base                      Option Period Number 1	
Title of Work Assignment/SF Site Name Health Effects Review			
Contractor: TOXSERVICES LLC		Specify Section and paragraph of Contract SOW SEE-PWS	
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance From 06/01/2011 To 05/31/2012	
Comments:			
<input type="checkbox"/> Superfund		Accounting and Appropriations Data	
		<input checked="" type="checkbox"/> Non-Superfund	
Note: To report additional accounting and appropriations data use EPA Form 1900-68A.			
SFO (Max 2) <input type="checkbox"/>			
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)
			Budget Org/Code (Max 7)
			Program Element (Max 9)
			Object Class (Max 4)
			Amount (Dollars)
			(Cents)
			Site/Project (Max 8)
			Cost Org/Code (Max 7)
1			
2			
3			
4			
5			
Authorized Work Assignment Ceiling			
Contract Period:		Cost/Fee:	
06/01/2010 To 05/31/2012		LOE: 270	
This Action:		400	
Total:		670	
Work Plan / Cost Estimate Approvals			
Contractor WP Dated:		Cost/Fee:	
		LOE:	
Cumulative Approved:		Cost/Fee:	
		LOE:	
Work Assignment Manager Name    Santhini Ramasamy		Branch/Mail Code:	
_____ (Signature)		_____ (Date)	
Project Officer Name    Shirley Harrison		Phone Number    202-566-1084	
_____ (Signature)		_____ (Date)	
Other Agency Official Name    Shirley Harrison		FAX Number:	
_____ (Signature)		_____ (Date)	
Contracting Official Name    Sandra Stargardt-Licis		Branch/Mail Code:	
_____ (Signature)		_____ (Date)	
		Phone Number: 202-566-1107	
		FAX Number:	
		Branch/Mail Code:	
		Phone Number: 202-566-1107	
		FAX Number:	
		Branch/Mail Code:	
		Phone Number: 513-487-2006	
		FAX Number:	



**PERFORMANCE WORK STATEMENT  
TOXSERVICES CONTRACT #EP-C-10-030  
WORK ASSIGNMENT #1-05, Amendment 2**

**TITLE:**      **Workgroup Perchlorate Health Effects Review**

**WORK ASSIGNMENT MANAGER:**      **Santhini Ramasamy**  
Mail Code 4304T, Room # 5233 Q  
Office of Water, Office of Science and Technology  
Health and Ecological Criteria Division  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460  
Telephone: 202-566-1084; Fax: 202-566-1140

**ALTERNATE EPA WAM:**                      **Melanie Young**  
Mail Code 4304T, Room #5231YY  
Office of Water, Office of Science and Technology  
Health and Ecological Criteria Division  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460  
Telephone: 202-250-8817; Fax: 202-566-1140

**PERIOD OF PERFORMANCE:**      Work Assignment (Amd) Issuance through May 31, 2012

**LOE:**              **400 Hours**

**PURPOSE OF AMENDMENT:**      The purpose of this amendment is to add new tasks, hours and funding to the existing work assignment. Any technical direction under this work assignment amendment, the EPA WAM will provide to the PO and CO within 5 days.

**BACKGROUND:**      same as the original work assignment

**QUALITY ASSURANCE:**      same as the original work assignment

**WORKPLAN AND MPRs:**      same as the original work assignment

**TASKS:**

Task 2a: The contractor shall integrate the outputs from WA 1-04 in regard to new literature review (narrative format) and graphical array across human health and animal studies related to perchlorate exposure in developing the draft HESD. The deliverable is the same as the original work assignment (Task 2).

Task 3a: The EPA WAM will provide to the contractor comments from Agency reviewers. The contractor shall incorporate comments and prepare written response to comments, if required, prior to the development of final HESD document and submit to the EPA WAM. The deliverable is the same as the original work assignment (Task 3).

Task 4: The contractor shall provide technical support to the EPA WAM for the External Review (e.g., SAB) of the HESD.

Task 5: The EPA WAM will provide to the contractor comments from external reviewers. The contractor shall incorporate the comments from external reviewers and the public in the final HESD document and prepare response to comments and submit to the EPA WAM.

#### **SCHEDULE AND DELIVERABLES:**

<b>Task</b>	<b>Task Description</b>	<b>Deliverable Due date</b>
Task 1	Work Plan	Within 15 days of receipt of work assignment
Task 2	Draft document preparation	40 days after receipt of technical direction from EPA WAM
Task 3	Final document preparation and Response to Comments	8 days after receipt of technical direction from EPA WAM
Task 4	External Review Support	5 days after receipt of technical direction from EPA WAM
Task 5	Incorporation of External reviewers Comments and Response to Comments	15 days after receipt of technical direction from EPA WAM

**TRAVEL:** No travel is required under this work assignment.

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>		Work Assignment Number 1-05								
		<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000003								
Contract Number EP-C-10-030	Contract Period   06/01/2010 To   05/31/2012	Title of Work Assignment/SF Site Name Perchlorate HESD								
Contractor TOXSERVICES LLC		Specify Section and paragraph of Contract SOW 1-05 Amendment 3								
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance  From   06/01/2011 To   05/31/2012								
Comments:										
<input type="checkbox"/> Superfund    Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:		670				
06/01/2010 To 05/31/2012										
This Action:						250				
Total:						920				
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee:		LOE:				
Cumulative Approved:				Cost/Fee:		LOE:				
Work Assignment Manager Name   Santhini Ramasamy						Branch/Mail Code:				
_____ (Signature)    (Date)						Phone Number   202-566-1084				
						FAX Number:				
Project Officer Name   Shirley Harrison						Branch/Mail Code:				
_____ (Signature)    (Date)						Phone Number:   202-566-1107				
						FAX Number:				
Other Agency Official Name						Branch/Mail Code:				
_____ (Signature)    (Date)						Phone Number:				
						FAX Number:				
Contracting Official Name   Sandra Stargardt-Licis						Branch/Mail Code:				
_____ (Signature)    (Date)						Phone Number:   513-487-2006				
						FAX Number:				

**PERFORMANCE WORK STATEMENT  
TOXSERVICES CONTRACT #EP-C-10-030  
WORK ASSIGNMENT #1-05, Amendment 3**

**TITLE: Workgroup Perchlorate Health Effects Review**

**WORK ASSIGNMENT MANAGER:**

**Santhini Ramasamy**  
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Office of Water, Office of Science and Technology  
Health and Ecological Criteria Division  
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Telephone: 202-566-1084; Fax: 202-566-1140

**ALTERNATE**

**WAM: Melanie Young**  
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Office of Water, Office of Science and Technology  
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**PERIOD OF PERFORMANCE:** Work Assignment Issuance through May 31, 2012

**PWS TASKS:** 2.1 - 2.3, 2.5, 2.7 - 2.9, 3.1.1 - 3.1.12, 3.3.1, 3.4, 3.5, 3.6.1, 3.6.2.

**Total LOE: 250 Hours**

**PURPOSE OF AMENDMENT:**

The purpose of this amendment is to add additional hours and funding to update and provide technical editing, consistency review and science support of the draft Health Effects Support Document in preparation for the Agency's perchlorate workgroup review and for external SAB review. The schedule and deliverables remain the same as in the original SOW and in the previous amendments.

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 1-07			
Contract Number EP-C-10-030						Contract Period 06/01/2010 To 05/31/2012 Base Option Period Number 1			
Contractor TOXSERVICES LLC						Title of Work Assignment/SF Site Name cumulative risk - Nitrosamines			
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Specify Section and paragraph of Contract SOW 2.3, 3.1, 3.4, 3.5			
Comments:						Period of Performance From 06/01/2011 To 05/31/2012			
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund         <div style="text-align: center;">Accounting and Appropriations Data</div> <input checked="" type="checkbox"/> Non-Superfund       </div>									
SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A.									
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars) (Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1									
2									
3									
4									
5									
Authorized Work Assignment Ceiling									
Contract Period:		Cost/Fee:		LOE:					
06/01/2010 To 05/31/2012				0					
This Action:				855					
Total:				855					
Work Plan / Cost Estimate Approvals									
Contractor WP Dated:				Cost/Fee:		LOE:			
Cumulative Approved:				Cost/Fee:		LOE:			
Work Assignment Manager Name Joyce Donohue _____ (Signature) (Date)						Branch/Mail Code: Phone Number 202-566-1098 FAX Number:			
Project Officer Name Shirley Harrison _____ (Signature) (Date)						Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:			
Other Agency Official Name Shirley Harrison _____ (Signature) (Date)						Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:			
Contracting Official Name Sandra Stargardt-Licis _____ (Signature) (Date)						Branch/Mail Code: Phone Number: 513-487-2006 FAX Number:			

**PERFORMANCE WORK STATEMENT  
TOXSERVICES CONTRACT #EP-C-10-030  
WORK ASSIGNMENT # 1-07**

**WORK ASSIGNMENT:** Cumulative Risk for Regulatory Determination 3:  
Nitrosamines as a Group

**WORK ASSIGNMENT  
MANAGER (WAM):**

**Joyce Donohue**

Office of Water, Office of Science and Technology  
Health and Ecological Criteria Division (MC 4304T)

U.S. Environmental Protection Agency

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**For Delivery (FEDEX or UPS)**

**Use Address below:**

U.S. Environmental Protection Agency

OW/OST/HECD (4304-T)

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Washington, DC 20460

**PERIOD OF PERFORMANCE:** Work Assignment Issuance through May 31, 2012

**SOW TASKS:** 2.3, 3.1.1, 2, 3.2, 3.1.3, 3.1.4, 3.1.5, 3.1.9, 3.1.10, 3.1.12, 3.4, 3.5

**LOE HOURS:** 855 Hours

**BACKGROUND**

The Safe Drinking Water Act, as amended in 1996 (SDWA) requires EPA to publish a Contaminant Candidate List (CCL) of chemicals that are not subject to any proposed or promulgated National Primary Drinking Water Regulations (NPDWRs), are known or anticipated to occur in public water systems (PWSs), and may require regulation under SDWA. SDWA also directs EPA to determine whether to regulate at least five contaminants from the CCL every five years; this is known as the Regulatory Determination process. Six nitrosamines are presently being considered as candidates for Regulatory Determination 3. The six nitrosamines are:

- N-nitrosodibutylamine (NDBA)
- N-nitrosodiethylamine (NDEA)
- N-nitrosodimethylamine (NDMA)
- N-nitrosodi-n-propylamine (NDPA)



- N-nitrosomethylethylamine (NMEA)
- N-nitrosopyrrolidine (NPYR)

One option is to regulate these chemicals as a group since all except for NDPA have been detected in public drinking water systems during the Unregulated Contaminant Monitoring Rule 2 sample collection and analysis period. Consideration is also being given to considering the three most prevalent NDMA, NDEA, and NPYR individually.

Each of the nitrosamine listed above causes cancer in animal studies. The EPA (2005) *Supplemental Guidance for Assessing Susceptibility from Early Life Exposure to Carcinogens* considers NDEA and NDMA to cause cancer via a mutagenic mode of action. All six chemical produced reactive electrophiles following Cyp P450 oxidation that are capable of forming adducts with one or more of the DNA bases. One study, Berger et al. (1987), has evaluated the tumorigenicity of NDEA, NPYR, and N-nitrosodiethanolamine individually and as a mixture and found the tumor response to be additive. The additivity of the response provides some justification for considering them as a group when they co-occur in drinking water. For this reason the Health and Ecological Criteria Division is requesting assistance from the contractor in developing a cumulative risk assessment for the CCL3/UCMR2 nitrosamines through this Work Assignment (WA).

The outline for the cumulative risk assessment is provided as attachment 1. The EPA WAM will be working with the contractor in preparing the document. Certain Sections will be completed by EPA while others will be the responsibility of the contractor. Sections presently considered to be the responsibility of the contractor are italicized in the present outline. This division of labor may change as the WA progresses. Rita Schoeny Ph.D. is the technical expert for this effort and Joyce Donohue Ph.D. is the EPA WAM for this work assignment.

## **QUALITY ASSURANCE**

The tasks in this work assignment require the use of primary and/or secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must supplement their quality assurance project plan (QAPP) to assure the quality of the secondary data used under this work assignment if necessary. When such a project-specific processes are necessary they should be noted in the workplan and monthly reports.

## **STATEMENT OF WORK**

### **TASK 1: Work Plan and Monthly Progress Reports**

Task 1 provides the funding for preparation of the Work Plan, any subsequent amendments and other activities that apply to the work plan in its entirety including the preparation of the required monthly reports and documentation for quality assurance activities.

The contractor shall prepare and submit the Work Plan in response to this work assignment request. The Work Plan shall include a detailed schedule, with deliverables, a list of the key individuals who will be involved in the technical aspects of the project, as well as conflict of

interest and quality assurance declarations. Descriptions of the professional qualifications of personnel involved in the work assignment do not have to be subdivided by Task and can be included in an appendix to the Work Plan. The cost estimate shall include the direct staff costs associated with the level of effort hours as well as any itemized indirect costs, but does not have to be subdivided by Task. The contractor shall prepare monthly reports for this work assignment and include in those reports and adjustments to their quality assurance plan necessitated by unanticipated needs for specialized quality assurance measures. A final QA report will be submitted with the document drafts for public comment.

## **Task 2: Supplemental Literature Searches and Document Retrieval**

The EPA WAM will be using its library resources in order to obtain references for the Cumulative Risk Assessment document. Focused follow-up literature searches for some papers may be required. The technical expert will submit a description of follow-up search needs to the EPA WAM. The EPA WAM will provide the description to the contractor. Assume two minor searches when crafting the Work Plan and retrieval of up to 15 papers when developing the cost estimate.

## **Task 3: Preparation of Assigned Sections from the Cumulative Risk Document Outline**

The contractor shall prepare draft sections of the Cumulative risk Assessment document for review. The initial cost proposal should be based on the anticipated effort for only those sections of the document presently marked as the responsibility of ToxServices. The EPA WAM will provide all references other than those that the contractor is asked to obtain in Task 2. The contractor can request conference calls with the EPA WAM to discuss questions or obtain guidance on section development. If needed, funding will be added through an amendment in additional sections are added to the Cumulative Risk document.

## **Task 4: Revision to Draft Documents and Response to Reviewer Comments.**

The contractor shall respond to comments from the Technical Expert, the OST QC reviewer, the peer reviewers, OGWDW, and/or OMB as appropriate. Submit individuals document sections for review as they are completed. Responses will include making alterations to the draft documents as appropriate and providing written responses to reviewer comments as needed. Written technical directions for these activities will be provided to the contractor via the EPA WAM. Assume four cycles of review. Any technical direction under this work assignment, the EPA WAM will provide to the PO and CO within 5 calendar days.

## **Task 5: Prepare Tables of Mutagenicity/Genotoxicity Data**

The Cumulative Risk document will include Tables that summarize the mutagenicity and geneotoxicity data in a prescribed manner to support the mode of action framework. The contractor shall prepare the Tables for each of the six nitrosamines. The EPA WAM will provide the references that are not currently held by the contractor, the format for the Tables, and Technical directions for preparing them (see attachment for Table format). Assume one cycle of

review and revision for the Tables. Completion of the Tables before working on Subsection of Section 3 may be helpful. Estimate Table entries for 80 papers.

#### **Task 6: Technical Support.**

This Task will provide the technical assistance that HECD will need to prepare materials derived from the cumulative risk document for occasions such as management briefings, stakeholder meetings, OMB review etc. Written technical directions will be provided by the EPA WAM, for each request. The anticipated activities that will be covered by this task will include:

- Graphics support for PowerPoint presentations (assume requests for two presentations)
- Researching specific questions posed to HECD by the Regulatory Determination Work Group, OW management and/or OMB (assume two such occurrences per chemical))
- Fact sheet development (assume one occasion which will involve providing health-effects information for inclusion in the OGWDW Regulatory Determination Proposal Fact sheet).

#### **SCHEDULE AND DELIVERABLES:**

Task 1: Two Weeks after receiving the Work Assignment request

Task 2: As needed.

Task 3: Deliver the draft sections for review as they are completed. All sections should be submitted for their first level of review by mid August.

Task 4: Three weeks after receiving HECD review comments and one week after receiving comments via the EPA WAM from OGWDW and/or OMB.

Task 5: First draft of the Tables by the middle of August.

Task 6: As needed.

## Attachment 1

### Outline: Cumulative Risk Assessment Support Document for Nitrosamines

To be done in house

Forward – Boilerplate (see att 1)

Acknowledgement: (see att 2)

Table of Contents

List of Tables

List of Figures

Abbreviations and Acronyms

1.0 Executive Summary (prepared at end of process)

#### **2.0 Justification for developing cumulative risk**

##### **2.1 Brief description of cumulative risk**

###### **2.1.1 Definition**

###### **2.1.2 Authorities for doing cum risk**

###### **2.1.2.1 SDWA**

###### **2.1.2.1.1 Citation of section re mixtures**

###### **2.1.2.1.2 Drinking water plan**

###### **2.1.2.2 FQPA – water as food. Note that this is for pesticides only and n-amines are disinfection by-products**

##### **2.2 Framework for Human Health Risk**

###### **2.2.1 Description in Silver Book – include published figure**

###### **2.2.2 RAF development of EPA Framework for Human Health Risk**

*Assessment (note document is in draft but may be final in fall or at end of calendar 2011).*

###### **2.2.2.1 Include diagram from presentation (att3)**

##### **2.3 Application of Framework for Human Health Risk to nitrosamines (to be done in-house)**

3.0 Basis for cumulative risk of nitrosamines

#### **3.1 Intro – risk assessment community recognizes several bases for combining chemicals to assess risk**

##### **3.1.1 Common mode of action (MOA)**

###### **3.1.1.1 Cite Mixtures Guidelines, Mixtures TSD, Silver Book**

##### **3.1.2 Common adverse outcome**

###### **3.1.2.1 Cite NRC Phthalates**

##### **3.1.3 Other practical approaches**

###### **3.1.3.1 Cite Water plan re common monitoring, common treatment**

#### **3.2 Brief description of nitrosamines**

##### **3.2.1 Why found in water**

##### **3.2.2 Health effects –**

- 3.2.2.1 brief, refer to the HESDs*
- 3.2.2.2 Likely to be human carcinogens*
- 3.2.2.3 Genotoxic and mutagenic*
- 3.2.2.4 No data to support RfDs for . . .*

### **3.3 Basis for cumu risk for nitrosamines**

#### **3.3.1 Nitrosamines have a common mode of action**

*3.3.1.1 Note that this is the preferred basis in EPA Mixtures Guidelines and wide acceptance (e.g. FQPA)*

*3.3.1.2 Mode of action for nitrosamines is mutagenicity (do in depth for NDMA and NDEA; make SAR arguments for the other nitrosamines)*

##### **3.3.1.2.1 Present key events**

*3.3.1.2.1.1 Key events are metabolism, generation of reactive metabolites, DNA adduct formation (give specifics), misreplication on damaged DNA template or misrepair of DNA damageDNA repair leading to mutation, mutations in critical genes results in enhanced DNA/ Cell replication*

*(adapted from Preston and Williams 2005 as cited in Jarabek et al 2009 – Table 1).*

*3.3.1.2.2 Present data in support of MOA following modified Hill Criteria -- do in depth for NDEA and NDMA. For others use graphic to indicate data present or not*

*3.3.1.2.3 Alternative MOA – use information on hepatotoxicity from NDMA section 7.3.3.1 – including discussion of elevation of hepatic  $Ca^{2+}$ .*

##### **3.3.1.2.4 Relevance of MOA to humans**

*3.3.1.2.4.1 No qualitative difference in key events (no data to think otherwise)*

*3.3.1.2.4.2 Quantitative differences do not preclude relevance.*

#### **3.3.2 Health endpoint for cumulative risk is carcinogenicity**

*3.3.2.1 Response addition is appropriate means of combining -- add risks*

*3.3.2.1.1 Cite Mixtures Guidelines and TSD as basis*

*3.3.2.1.2 Cite Berger for NDMA (?) and other nitrosamines.*

*3.3.2.2 Brief description and/ or table of slope factors from HESDs*

### **3.4 Areas of Uncertainty (To be done in-house)**

#### **3.4.1 More data for MOA for some nitrosamines**

3.4.1.1 But SAR is a reasonable basis as well

3.4.1.2 Metabolism via alpha hydroxylation yielding carbocations  
applicable to nitrosamines under consideration

3.4.2 Describe uncertainties in slope factor derivation – refer to HESDs

3.4.3 Present data on interactions among nitrosamines. Additivity is reasonable  
default.

#### ***4.0 Application of response addition for a suite of nitrosamines in drinking water***

##### ***4.1 Options***

***4.1.1 I add risks of all measured nitrosamines (develop simple algorithm)  
based on available info re occurrence***

***4.1.2 Consider all measured nitrosamines to be equivalent to NDMA***

##### ***4.2 Example calculation***

5.0 Regulatory determination discussion – to be provided at end of process

#### ***6.0 References***

***7.0 Appendices – tables of genotoxicity, mutagenicity data for each nitrosamine. See att 4***



### Format for Organizing the Assays of Mutagenicity

These examples are illustrative rather than comprehensive. The assays included, as well as the organization thereof, depend on the quality and quantity of assay available.

<b><i>In vitro</i> Assays Test System</b>	<b>Concen- trations</b>	<b>Cytotoxicity: concentration observed <sup>1</sup></b>	<b>Duration of Exposure</b>	<b>Results With metabolic activation (+ S9)</b>	<b>Results Without metabolic activation (- S9)</b>	<b>Conform to relevant guideline or Acceptability of test</b>	<b>Reference</b>
<b><i>Gene Mutation</i></b>							
<b>Bacterial</b>							
<i>Salmonella</i> , reverse mutation							
<i>E. coli</i> , reverse mutation							
<b>Mammalian</b>							
CHO gene mutation, <i>hprt</i> locus							
Mouse L5178Y, <i>tk</i> locus							
<b><i>Chromosome Mutation</i></b>							
Micronucleus assay							
Chromosomal aberrations							
<b><i>DNA Effects</i></b>							
<b>Mammalian</b>							
Unscheduled DNA synthesis							
Sister chromatid exchanges							
Comet assay							
DNA adduct analysis							
<b>Lower Eukaryote</b>							
<i>Saccharomyces cerevisiae</i> , gene conversion							
<b><i>Other in vitro assays</i></b>							
1.							
2.							

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>		Work Assignment Number 1-08 <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:								
Contract Number EP-C-10-030	Contract Period 06/01/2010 To 05/31/2012 Base                      Option Period Number 1	Title of Work Assignment/SF Site Name Updates to HH AWQC								
Contractor TOXSERVICES LLC		Specify Section and paragraph of Contract SOW 3.1.2								
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance  From 06/01/2011 To 05/31/2012								
Comments:										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period: 06/01/2010 To 05/31/2012		Cost/Fee:		LOE: 0						
This Action:				355						
Total:				355						
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:		Cost/Fee:		LOE:						
Cumulative Approved:		Cost/Fee:		LOE:						
Work Assignment Manager Name Heidi Bethel						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number 202-566-2054				
						FAX Number:				
Project Officer Name Shirley Harrison						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number: 202-566-1107				
						FAX Number:				
Other Agency Official Name Elizabeth Doyle						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number: 202-566-0056				
						FAX Number:				
Contracting Official Name Sandra Stargardt-Licis						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number: 513-487-2006				
						FAX Number:				

**PERFORMANCE WORK STATEMENT  
TOX SERVICES CONTRACT # EP-C-10-030  
WORK ASSIGNMENT #1-08**

**TITLE:** Updates to Human Health Ambient Water Quality Criteria

**WORK ASSIGNMENT MANAGER:**

*Mailing Address:*

Heidi Bethel (MC: 4304T)  
Health & Ecological Criteria Division  
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**ESTIMATED LOE:** 355 Hours

**SOW SECTION:** 3.1.2

**PERIOD OF PERFORMANCE:** Work Assignment Issuance to May 31, 2012

**BACKGROUND:**

In 2000, EPA published the *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)* (EPA-822-B-00-004, [http://water.epa.gov/scitech/swguidance/standards/upload/2005\\_05\\_06\\_criteria\\_humanhealth\\_method\\_complete.pdf](http://water.epa.gov/scitech/swguidance/standards/upload/2005_05_06_criteria_humanhealth_method_complete.pdf)). The 2000 Methodology describes EPA's policies and procedures for calculating human health ambient water quality criteria and updated EPA's previous methodology published in 1980. Significant updates in the 2000 Methodology included the addition of a relative source contribution (RSC) to estimate exposure to a chemical from other sources besides water and fish; an increase in the daily fish consumption estimate from 6.5 g/day to 17.5 g/day; and a recommendation for states to use local bioaccumulation factors (BAF) and consumption data for fish, when it is available. Since the publication of the 2000 Methodology document, EPA has published several Federal Register notices (2002 FR, Vol. 67, No. 249; 2009 FR, Vol. 74, No. 110) announcing "partial" updates to existing human health ambient water quality criteria. In these updates, criteria have been recalculated using updated toxicity values (reference doses and cancer slope factors) from EPA's Integrated Risk Information System (IRIS) and relative source contribution values calculated by EPA's drinking water program. No other new criteria have been developed since the publication of the 2000 Methodology. At this time, the Office of Water is interested in collecting and prioritizing data from secondary sources that may be available to update existing criteria and generate new criteria for use by States and Tribes in their water quality standards programs. The goal of this work is to recommend a faster approach to generate human health ambient water quality criteria and support documents, and to streamline the process for new criteria recommendations.

**QUALITY ASSURANCE:**

The tasks in this work assignment require only the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must supplement their quality assurance project plan (QA PP) to assure the quality of the secondary data used under this work assignment. The project specific quality assurance requirements must be addressed in the work plan, monthly progress reports, and final report as specified under Task 1 below. The tasks in this Work Assignment (WA) do not require primary data from environmental measurement and/or generation of laboratory data.

## **STATEMENT OF WORK**

The purpose of this work assignment is to collect data from secondary sources that may be available for updating current criteria values or generating new human health criteria values; prioritizing criteria for updates or new criteria; and drafting a straw-man criteria document for chemical criteria based on already peer reviewed secondary sources of data.

### **Task 1: Prepare a Work Plan**

Task 1 provides the funding for preparation of the workplan, any subsequent amendments and other activities that apply to the work plan in its entirety including the preparation of the required monthly reports and documentation for quality assurance activities.

The contractor shall prepare and submit a work plan outlining the work to be conducted to collect data for criteria updates, prioritizing data; and creating a straw-man document in response to this work assignment request. The work plan shall include a detailed schedule, with deliverables, a list of the key individuals who will be involved in the technical aspects of the project, as well as conflict of interest and quality assurance declarations. Descriptions of the professional qualifications of personnel involved in the work assignment do not have to be subdivided by Task and can be included in an appendix to the Work Plan.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs' broken out by the tasks in this WA.

A brief QA summary must be provided in the final report of this work assignment. This QA summary will briefly describe this work assignment compliance to the contract-level QAPP, what additional significant project-specific QA issues have occurred and how these have been addressed. In addition, it also serves as a pointer indicating the locations (e.g. monthly reports, etc) of more detailed description of the QA processes that occurred during the course of this work assignment. This QA section can be an appendix or a subsection in the final deliverable.

### **Task 2: Collect and prioritize data from secondary sources**

The contractor shall collect, prioritize and summarize data from secondary sources available for

updates to existing criteria and generation of new criteria. Data may include information on toxicity factors (reference doses and cancer slope factors), bioconcentration factors or bioaccumulation factors; and relative source contribution. Data sources may include, but will not be limited to: data from available peer-reviewed scientific literature sources; data from other EPA offices and programs (OPP, OSWER, ORD/IRIS, OGWDW drinking water MCLGs); data from other Agencies such as ATSDR, WHO and Health Canada. Data may also include modeled or estimated data such as estimated BCFs from OPPT.

Based on availability of data, the contractor shall organize the data collected and recommend a prioritization schedule for criteria updates and new criteria generation. Prioritization will depend on availability of data for a partial update to existing criteria or generation of new criteria (BCF, toxicity factors and possibly a relative source contribution).

### **Task 3: Creation of a straw-man draft criteria document**

The contractor shall create a draft criteria straw-man document to use as a template for new criteria development. The document should specify the minimum reporting necessary for a criteria document based entirely on secondary peer-reviewed data sources. The straw-man document may follow the format of the 2000 Human Health Methodology, the older 1980 criteria documents, or some combination of the two. The web link to the 1980 Criteria Documents: [http://water.epa.gov/scitech/swguidance/standards/criteria/ambientwqc\\_index.cfm](http://water.epa.gov/scitech/swguidance/standards/criteria/ambientwqc_index.cfm)

### **DELIVERABLES AND SCHEDULE**

<b>Task 1:</b>	<b>Prepare a Work Plan</b>	<b>Due 15 days after receipt of WA</b>
<b>Task 2:</b>	<b>Collect, prioritize and summarize data available from secondary sources</b> <ul style="list-style-type: none"> <li>• BCFs/BAFs</li> <li>• Toxicity Factors</li> <li>• Relative source contribution</li> </ul>	<b>Due approximately September 15, 2011 or as communicated with the EPA WAM</b>
<b>Task 3:</b>	<b>Creation of a straw-man draft criteria document</b>	<b>Due approximately September 15, 2011 or as communicated with the EPA WAM</b>

### **SPECIAL REPORTING REQUIREMENTS**

Key contract staff should maintain regular communication with the work assignment manager to describe progress and status of data collection, analyses and development of the straw man document. The contractor shall contact the work assignment manager by phone (202-566-2054) with any questions or problems as soon as they arise to ensure rapid resolution. The contractor shall provide the EPA WAM, either electronically or by fax, any/all forms documenting QA/QC of data or documents submitted as deliverables.

**REFERENCES:**

Human Health Ambient Water Quality Calculation Matrix which shows the parameters used to calculate the current human health ambient water quality criteria (attached separately).